

Application Number 10/730,878
Amendment dated April 11, 2008
Response to Office Action mailed January 17, 2008

REMARKS

This Amendment is responsive to the Office Action dated January 17, 2008. Applicant has amended claims 1, 5, 9, 17, and 19, and canceled claim 11. Claims 1-10 and 12-20 are pending.

Claim Rejections Under 35 U.S.C. §§ 102(e) and 103(a)

In the Office Action, claims 1-20 were rejected under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over O'Hara (U.S. Patent No. 7,110,819). In addition, claims 7, 8, 11, 12 and 18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over O'Hara. Claims 1-20 were also rejected under 35 U.S.C. § 103(a) as being unpatentable over Berrang et al. (U.S. Patent No. 6,358,281, hereinafter "Berrang"). Applicant respectfully traverses these rejections of the claims, particularly to the extent the rejections may be considered applicable to the amended claims. The cited references fail to disclose or suggest each and every element of Applicant's claims.

O'Hara

Independent Claims 1 and 9

For example, O'Hara fails to teach or suggest an overmold that is at least partially flexible to allow relative motion between modules of a medical device, as recited by Applicant's independent claims 1 and 9 as amended. According to the Office Action, the housing sections 202, 204 disclosed by O'Hara comprise a first material of an overmold and the header body 252 comprises a second material of the overmold that "encapsulates each of the housings."¹ Applicant respectfully disagrees with the Office Action's characterization of the housing sections 202, 204 and header body 252 as an overmold.

The header body 252, either alone or with the housing sections 202, 204, does not at least partially encapsulate each of the housings of interconnected modules, and, therefore, cannot be considered a part of an overmold. O'Hara discloses that an implantable cardioverter defibrillator

¹ Office Action at p. 3, item 6.

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(ICD) includes a lower housing portion 202, an upper housing portion 204, and internal circuitry and electrical components 206. As an initial matter, Applicant notes that O'Hara does not disclose that the internal circuitry and electrical components 206 comprise at least two interconnected modules, much less interconnected modules that each comprise a respective housing, as required by Applicant's claims. While O'Hara states that the housing portions 202, 204 are welded closed to form a hermetic seal and hold the components 206 in a chamber defined by the housing,² O'Hara does not disclose that the components of the ICD include respective housings in addition to the housing portions 202, 204, as would be required in view of the Examiner's interpretation of housing portions 202, 204 being part of an overmold.

The Office Action reasoned that it is obvious to enclose "various stimulator components such as the hybrid, battery, delivery capacitor, and communications circuitry in different housings."³ Applicant respectfully disagrees with the Office Action's assertion of obviousness. If the Office Action is taking official notice of facts not in the record or relying on common knowledge to support this assertion of obviousness, Applicant respectfully requests the Examiner provide documentary evidence to support the apparent assertion of knowledge in the art. As provided in the M.P.E.P. 2144.03, it is appropriate to take official notice of facts without supporting documentary evidence or to rely on common knowledge in the art in making a rejection where the facts asserted to be well-known are capable of instant and unquestionable demonstration as being well-known. In the present case, Applicant disagrees that an assertion that it is obvious to enclose "various stimulator components" in different housings is capable of instant and unquestionable demonstration as being well-known. For example, as disclosed by O'Hara, the components 206 are enclosed in a single, common housing defined by the housing portions 202, 204.

Even if it is obvious to enclose "various stimulator components such as the hybrid, battery, delivery capacitor, and communications circuitry in different housings," as proposed by the Office Action⁴, an assertion with which Applicant disagrees and for which the Examiner provides no evidentiary support, the header body 252 in no way constitutes a part of an overmold

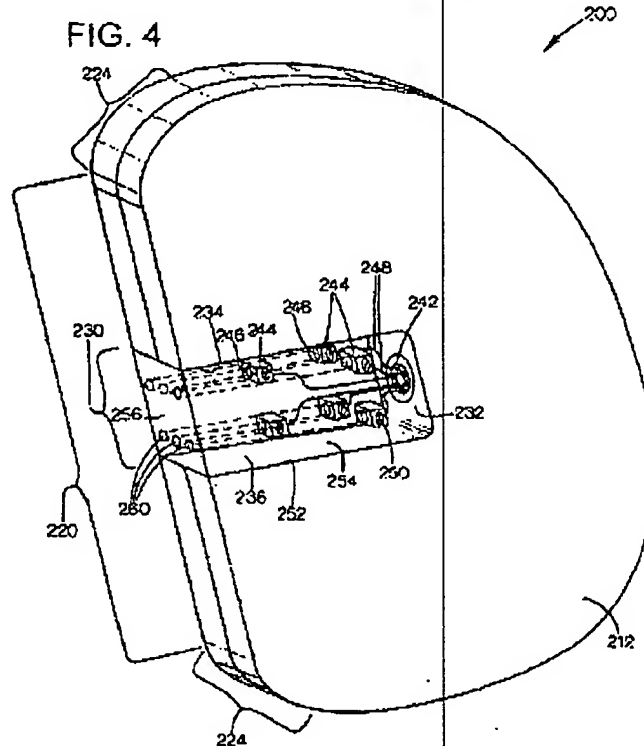
² O'Hara at col. 7, ll. 29-32 and col. 8, ll. 61-63.

³ Office Action at p. 4, item 7.

⁴ Office Action at p. 4, item 7.

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that at least partially encapsulates housings of modules, as required by Applicant's claims. O'Hara discloses that the housing portions 202, 204 are welded to seal the components 206 in a chamber defined by the housings 202, 204. When the housing portions 202, 204 are welded together, they enclose the components 206 and the outer surfaces of the housing portions 202, 204 define an inlet 230⁵, as shown in FIG. 4 of O'Hara, which is reproduced below.



O'Hara discloses that the header body 252 is formed to fill the negative space, i.e., the inlet 230, defined by the outer surface of the housing.⁶ O'Hara explicitly describes the header body 252 as having "an exterior surface flush with the exterior housing surfaces."⁷ The housing portions 202, 204 appear to completely enclose the components 206, and the header body 252 is external to the housing portions 202, 204. Accordingly, it is unclear how the header body 252 may be reasonably characterized to be a part of an overmold, as recited by Applicant's

⁵ O'Hara at col. 7, ll. 55-57.

⁶ *Id.* at col. 8, l. 15.

⁷ *Id.* at col. 8, ll. 15-17.

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independent claim 1, because header body 252 does not at least partially encapsulate housings of interconnected modules.

Independent claims 1 and 9 as amended clarify that an overmold is at least partially flexible to allow relative intermodule motion. Accordingly, even if the housing sections 202, 204 are considered to be an overmold and the components 206 constitute modules, the housing sections 202, 204 are made of metal and do not permit motion between the components 206.⁸ O'Hara discloses that its ICD includes a "robust" metal housing⁹ that makes primary contact with a flat surface and bears most or all of the stresses from the impact, thereby protecting the header body 252 from the stresses.¹⁰ Modifying the housing sections 202, 204 to be at least partially flexible would appear to render the O'Hara ICD housing inoperable for its intended purpose. Accordingly, there is no suggestion or motivation to modify the O'Hara ICD housing to include an overmold that is at least partially flexible.¹¹

In addition, even if the header body 252 is a part of an overmold of the O'Hara ICD and the components 206 include interconnected modules comprising respective housings, assertions with which Applicant disagrees, O'Hara does not disclose that the header body 252 allows relative motion between housings of the components 206. It is unclear how the header body 252 would permit intermodule motion. For example, the header body 252 is external to the rigid housings 202, 204, while the components 206 are enclosed within an internal space defined by the housings 202, 204. Therefore, elastomeric properties of the header body 252 would not influence the motion between any housings of the components 206.

Independent Claim 16

Applicant's independent claim 16 is directed toward an implantable medical device including at least two interconnected modules, each of the modules comprising a respective one of at least two housings to house the respective modules, and an overmold that partially

⁸ *Id.* at col. 8, l. 41.

⁹ *Id.*

¹⁰ *Id.* at col. 8, ll. 36-42.

¹¹ MPEP § 2143.01, citing *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

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encapsulates each of the housings and defines a frame configured to fix a position of the at least two interconnected modules relative to one another, the overmold comprising a lead connection module configured to accept an external lead, wherein the external lead is separable from the lead connection module. O'Hara also fails to disclose each and every element of independent claim 16.

For example, O'Hara fails to disclose or suggest an overmold that partially encapsulates at least two housings. The housing portions 202, 204 of the O'Hara ICD, which the Office Action characterized to be part of an overmold, completely enclose the electrical components 206. O'Hara discloses that "the housing portions may be welded "to seal the components 206 in a chamber defined by the housing" and define a hermetic seal.¹² Thus, even if the components 206 comprise at least two housings, an assertion with which Applicant disagrees, O'Hara fails to disclose or suggest an overmold that only partially encapsulates housings of interconnected modules. Accordingly, O'Hara fails to render Applicant's independent claim 16 obvious.

Dependent Claims

Claims 2-8 depend from independent claim 1, claims 10 and 12-15 depend from independent claim 9, and claims 17-20 depend from independent claim 16. For at least the reasons given above with respect to claims 1, 9, and 16, claims 2-8, 10, 12-15, and 17-20 are patentable over O'Hara. In addition, O'Hara fails to disclose or suggest each and every element of the dependent claims.

For example, O'Hara fails to disclose a control module comprising a hermetic housing, as recited by Applicant's claim 19 as amended. As discussed above, O'Hara does not disclose or even suggest that its internal circuitry and electrical components 206 are modules comprising housings. Moreover, O'Hara does not disclose that the internal circuitry and electrical components 206 comprises a hermetic housing that is separate from the housing portions 202, 204, which the Office Action characterized as an overmold. In contrast, Applicant's claim 19 requires both a control module comprising a hermetic housing and an overmold that at least partially encapsulates the housing of the control module.

¹² O'Hara at col. 7, ll. 29-32 and col. 8, ll. 61-63.

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Berrang

The Office Action also found that Berrang rendered claims 1-20 unpatentable under 35 U.S.C. § 103(a). Applicant maintains the arguments made in the previously-filed Amendment (dated October 2, 2007) regarding the rejection of the claims in view of Berrang. For example, Applicant maintains that Berrang fails to disclose modules comprising respective housings.

Independent Claims 1 and 9

Berrang also fails to disclose or suggest a lead connection module that is configured to accept an external lead, where the lead connection module comprises a feed-through wire that electrically couples to the external lead, as recited by Applicant's independent claims 1 and 9 as amended.

The Office Action characterized the "intersection of [bridge section] 6 and [junction] 16" as a lead connection module. Based on the Office Action's characterization of the intersection of bridge section 6 and junction 16 in Berrang as a lead connection module, it appears that the Office Action is also characterizing the cables 7 and 8 in FIG. 1 of Berrang as external leads. Applicant does not agree that cables 7 and 8 are external leads. However, even if, for purposes of argument only, the cables 7 and 8 in Berrang are external leads, Berrang does not teach that the cables 7 and 8 are separable from the intersection of bridge section 6 and junction 16, i.e., the "lead connection module" according to the Office Action, or that the "intersection of 6 and 16" includes a feed-through wire that electrically couples to an external lead.

According to the Office Action, "[r]egardless of whether the lead is removably attached to the housing, the system comprises a lead connection module . . . [that] comprises conductors that connect 16 with the internal electronics 21."¹³ However, Berrang does not disclose or even suggest that the junction 16 is connected to the internal electronics 21. Rather, Berrang merely states that the junction 16 is where the cables 7 and 8 merge. Nothing in Berrang suggests that separate feed-through wires that electrically couple to the cables 7, 8 are disposed within the bridge 6 and junction 16.

¹³ Office Action at p. 7, item 20.

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Applicant's claim 5, now amended, previously recited a lead connection module that includes a feed-through wire. In support of the rejection of claim 5, the Office Action reasoned that column 11, line 3 of Berrang disclosed a device including at least one feed-through wire. However, at column 11, line 3, Berrang merely states that "[t]he microphone casing 14 and electrode array 10 are connected to the housing sections 2 and 3 via junction 16 where cables 7 and 8 merge." Berrang does not disclose that its device includes a feed-through wire that connects to the cables 7, 8 within the junction 16.

Based on the lack of disclosure within Berrang related to the cables 7, 8 and the junction 16, it appears that the Office Action is relying on an inherent disclosure to support the assertion that the "intersection of 6 and 16" may reasonably be characterized as a lead connection module including a feed-through wire that electrically couples to an external lead. The fact that a certain characteristic may be present in the prior art is not sufficient to establish the inherency of that result or characteristic.¹⁴ The Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.¹⁵ No reasonable support has been provided for the determination that the "intersection of 6 and 16" includes a feed-through wire.

For example, based on the Berrang disclosure, it is possible that the cables 7, 8 extend through the "intersection of 6 and 16" in order to electrically couple to the components within the housing sections 2, 3. Berrang also discloses that the underside of each ceramic substrate 24, 25, which the Office Action characterized as being a "housing" for different modules, contain "a plurality of electrically insulated electrical lead-throughs."¹⁶ Accordingly, the Berrang device may not include a separate lead connection module that includes a feed-through wire, and the cables 7, 8 may directly couple to the housing sections 2, 3, which the Office Action characterized as "modules."

With respect to the claimed requirement that the lead connection module is configured to accept an external, separable lead, the Office Action acknowledged that Berrang does not disclose that "the lead is separable from the connection module," but reasoned that "it would

¹⁴ *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ.2d 1955, 1957 (Fed. Cir. 1993); MPEP 2112.

¹⁵ *Ex parte Levy*, 17 USPQ.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original); MPEP 2112.

¹⁶ Berrang at col. 11, ll. 48-50.

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have been obvious to one having ordinary skill in the art at the time the invention was made to modify Berrang's device by providing a detachable lead to provide the predictable result of simplifying implantation by allowing the lead and device to be implanted or explanted separately."¹⁷ Applicant respectfully disagrees with the Office Action's conclusion of obviousness. Berrang does not provide any disclosure to support the Office Action's allegation that one skilled in the art would be motivated to modify the cochlear prosthesis disclosed by Berrang to include separable leads. Furthermore, the Office Action failed to provide any support for the conclusion that cables 7, 8 that are separable from the housing sections 2, 3 would even be useful for surgical techniques for implanting a cochlear prosthesis.

Independent Claim 16

Berrang also fails to disclose or suggest an overmold that partially encapsulates housings of interconnected modules, as recited by independent claim 16.

The Office Action characterized the gold and epoxy layers in the Berrang device as an overmold. Even if the gold and epoxy layers are an overmold, an assertion with which Applicant disagrees, the gold and epoxy layers enclose the entire Berrang device, and, therefore, cannot be an overmold that partially encapsulates housings of interconnected modules, as required by Applicant's independent claim 1. Berrang discloses that its components require a "hermetic or hermetic like sealing on all surfaces,"¹⁸ and in order to achieve such a seal, a thin coating of vacuum deposited gold is applied to the components.¹⁹ Berrang states that "it is essential to hermetically encapsulate the internal components" with the gold layer.²⁰

Dependent Claims

Claims 2-8 depend from independent claim 1, claims 10 and 12-15 depend from independent claim 9, and claims 17-20 depend from independent claim 16. For at least the reasons given above with respect to claims 1, 9, and 16, claims 2-8, 10, 12-15, and 17-20 are

¹⁷ Office Action at pp. 6-7, item 18.

¹⁸ Berrang at col. 3, ll. 51-52.

¹⁹ *Id.* at col. 3, ll. 60-65.

²⁰ *Id.* at col. 11, ll. 55-60 and col. 12, ll. 16-20.

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patentable over Berrang. In addition, Berrang fails to disclose or suggest each and every element of the dependent claims.

For example, Berrang fails to disclose or suggest an implantable medical device comprising a control module comprising a hermetic housing, as recited by Applicant's claim 19 as amended. The Office Action characterized the elements 18 and 21, and the material surrounding the elements 18 and 21 as interconnected modules and the ceramic substrate 24 and snap dome 20 as a housing of the element 18 and the ceramic substrate 25 and snap dome 23 as the housing of the element 21.²¹ Even if the snap domes 20, 23 and ceramic substrates 24, 25 were housings of modules, an assertion with which Applicant disagrees, Berrang fails to disclose or suggest that the snap domes 20, 23 and ceramic substrates 24, 25, respectively, define a hermetic housing. In fact, Berrang specifically states that the epoxy that is used to coat and encapsulate that covers the components mounted to the ceramic substrates do "not provide a true hermetic or hermetic like seal."²² For this reason, Berrang et al. provides a single gold coating over the encapsulant surface.²³ Thus, Berrang et al. does not teach or suggest a device including at least two modules comprising separate housings, where a control module housing comprises a hermetic housing, as recited by Applicant's claim 19.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 1-10 and 12-20 under 35 U.S.C. §§ 102(e) and 103(a). Reconsideration and withdrawal of this rejection is respectfully requested.

²¹ Office Action at p. 6, item 18.

²² Berrang at column 3, lines 59-65.

²³ *Id.*

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CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date: April 11, 2008

By:

SHUMAKER & SIEFFERT, P.A.
1625 Radio Drive, Suite 300
Woodbury, Minnesota 55125
Telephone: 651.735.1100
Facsimile: 651.735.1102


Name: Jessica H. Kwak
Reg. No.: 58,975